UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP BARCODE No.: 415804; FILE SYMBOL No.: 83100-GL; PRODUCT NAME: Emamectin Benzoate 4% SL; DECISION No.:483360; PC Code(s): 122806; ACTION CODE: R310; FOOD Use: No

DATE OUT:

April 8, 2014

SUBJECT:

End Use Product Chemistry Review

Product name: Emamectin Benzoate 4% SI

FROM:

Shyam Mathur, Ph. D

Product Chemistry Team Leader

Technical Review Branch/RD (7505P)

TO:

Thomas Harris / Reuben Baris, RM 07

Insecticide-Rodenticide Branch / RD (7505P)

Company Name: Rotam Agrochemical Company

Formulation Type: Insecticide

INTRODUCTION:

The registrant has submitted an application to register the new end use product Emamectin Benzoate 4% SL. The registrant has submitted a CSF for basic formulation (dated 09-18-2013). The supporting product chemistry group A and group B data was submitted with MRID Nos. 492196-01 and 492196-02. The registrant has submitted a proposed product label. TRB has been asked to determine the acceptability of the proposed basic CSF and the supporting product chemistry data.

SUMMARY OF FINDINGS:

- 1. Name of Active Ingredient(s): Emamectin Benzoate (4.0%)
- 2. Has the registrant claimed substantial similarity to a registered product?

[] Yes; [X] No; [] NA; if yes, give the registration number of the cited product.

Rea. No.

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3.	All of the source materials of the active ingredient are derived from registered sources: [X] Yes [] No						
4.	All inert ingredients have been screened by IIAB and found to be approved for the proposed labeled Uses: [X] Yes; [] No						
5.	Confidential Statement of Formula(s):						
	[X] Proposed Basic - Dated: 09-18-2013; Resubmitted – Dated:						
	[] Proposed Alternate CSF – Dated:; Resubmitted – Dated:						
	Alternate CSF(s) complies with 40CFR§152.43: [] Yes; [] No; [X] NA						
6.	Product label						
 Ingredient statement: Nominal concentration of Al listed on CSF(s) concurs with produ (PR Notice 91-2). [X] Yes; [] No; if not, explain below: 							
	Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredient) [X] Yes; [] No; if not, explain below:						
	Metallic equivalent: [] Yes [X] NA Soluble arsenic: [] Yes [X] NA Isomeric ratios: [] Yes [X] NA Acid Equivalent: [] Yes [X] NA;						
	b. Health related sub statements: Product contains?						
	Petroleum distillate at > 10%: [] Yes [X] No [] NA Methanol at > 4%: [] Yes [X] No [] NA Sodium nitrate/Sodium Nitrite [] Yes [X] No [] NA						
,	 c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for flammability, explosive potential or electric insulator breakdown? [] Yes; [X] No 						
	Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)? [] Yes; [] No; [X] NA; if not, explain below						
7	d. Label requires an additional Storage and Disposal statement: [] Yes; [X] No; if yes explain below:						

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7. Group **A**:

Guideline No.	Study Title		Data submitted		TRB's Assessment of Data	MRID Nos.
			Yes No			MINID NOS.
830.1550	Product Ider	Х		Α	492196-01	
Description of materials used to produce the product			Х		А	492196-01
830.1650	Description of formulation process Discussion on the formation of impurities		х		Α	492196-01
830.1670			х		А	492196-01
830.1700	Preliminary analysis			NA		
		Standard certified limits	Х		А	
Certified limits	limits	Proposed Limits				
830.1750	(158.350)	Justification for wider limits				Basic CSF dated 09-18-2013
	Enforcement analytical method					492196-02
830.1800			Х		Α	With storage stability study

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request, NA = Not applicable, I = In progress; U = Upgrade

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8. Group **B**:

Guidelin e No.	Study Title	Value or Qualitative Description	TRB's Assessmen t of Data	MRID Nos.
830.6303	Physical State	Liquid	Α	492196-02
830.6314	Oxidation/reduction	Test substance was compatible with water, 10% monoammonium phosphate, Zn powder & kerosene. TS was incompatible to 10% potassium permanganate	A	492196-02
830.6315	Flammability	No flash point observed	Α	492196-02
830.6316	Explodability	NA	7.	102100 02
830.6317	Accelerated Storage stability	Stable for 2 weeks at 54°C in commercial container (F-HDPE)	Α	492196-02
830.6320	Accelerated Corrosion characteristics	No corrosion was seen on commercial container (F-HDPE) when stored for 2 weeks at 54°C	А	492196-02
830.7000	рH	5.02 (1% aqueous dilution) at 20°C	Α	492196-02
830.7100	Viscosity	37.3 mPa,s @ 20°C (100 rpm) 24.5 mPa.s @ 40°C (100 rpm)	Α	492196-02
830.7300	Density	1.0622 gm/ml @ 20°C	А	492196-02

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C. CONCLUSIONS:

The TRB has reviewed the proposed basic CSF and the supporting product chemistry data for the new end use product and has concluded:

- 1. The proposed CSF for basic formulation (dated 09-18-2013) is acceptable.
- 2. The submitted product chemistry data corresponding to the guidelines 830 series group A are acceptable including 830.1800 (enforcement analytical method). This study is submitted along with the accelerated storage stability under MRID No. 492196-02.
- 3. The product chemistry data submitted for the 830 series group B data (physical-chemical properties) are acceptable.
- 4. Since the proposed product was found to be non-compatible with the oxidizing agent, it is recommended that the registrant add the following warning under Physical-Chemical Hazards on the product label:

"Do not mix or allow coming in contact with oxidizing agent. Hazardous Chemical reaction may occur"